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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/585,006 | 06/28/2006 | Gary Lee Cantrell | 1675 WO/US | 6185 |
| 7590 | | 07/10/2008 | EXAMINER | |
| Jeffrey S Boon Mallinckrodt Inc 675 McDonnell Blvd PO Box 5840 St Louis, MO 63134 | | | MOORE, SUSANNA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/585,006 | Applicant(s) CANTRELL ET AL. |
| | Examiner SUSANNA MOORE | Art Unit 1624 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 April 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-11,15,17,28-30,32-41 and 43-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-11,15,17,30,37,40,41 and 48-50 is/are rejected.
- 7) Claim(s) 28,29,32-36,38,39,43-47,51 and 52 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No./Mail Date 7/20/06
- 4) Interview Summary (PTO-413)
 Paper No./Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 4/16/2008 is acknowledged. Group I, drawn to a process of making pyrazolopyrimidines, embraced by claims 1-11, 15, 17, 28, 51 and 52 was elected by Applicant. The traversal is on the ground(s) that Groups (I) and (II), as currently amended fall within the scope of claim 1. This is not found persuasive. Thus, claims 1-11, 15, 17, 28-30, 32-41 and 43-52 will be examined.

There are 36 claims pending and 36 under consideration. This is the first action on the merits. The application concerns a process of making pyrazolopyrimidine compounds in general.

Claim Objections

Claims 8, 36 and 47 are objected to because of the following informalities: abbreviations/acronyms are not appropriate in claims without the spelled-out meaning. Please define "DMF," "DMAC," "DMSO" and "THF." Appropriate correction is required.

Claim 52 is objected to because of the following informalities: the term "Oac" should be replaced with "OAc" in claim 52. Appropriate correction is required.

Claims 28, 29, 32-36, 38, 39, 43-47 and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 15, 17, 30, 37, 40, 41 and 48-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 9, 37 and 48, the terms "hexane compounds" and "xylene compounds" are vague. What are these hexane compounds or xylene compounds? Is hexane included in the definition of hexane compounds?

Regarding claims 9, 37 and 48, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the term "comprises" renders the products indefinite as the term "comprises" can be considered open-ended language when not clearly defined and therefore is including additional subject matter in the conjugate of claim 1 that is not described in the instant

Art Unit: 1624

specification and is not particularly pointed out or distinctly claimed. A claim to a chemical compound cannot be open-ended, but must be claimed with precision. This rejection can be overcome by amending the term "comprises to read "consisting of" in claim 15.

The term "phenyl(C₁-C₃)" is vague. A phenyl ring cannot have a C₁-C₃ carbon count. Thus, claim 15 is indefinite.

Claims 17, 30, 40, 41, 49 and 50 contains the trademarks/trade names Aliquat®336, ALKANOL®s and Indiplon™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe phase transfer catalysts and compounds and, accordingly, the identification/description is indefinite.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process of making pyrazolo[1,5-a]pyrimidines of Formula 1 in a two-phase system, does not reasonably provide enablement for a process of making substituted

Art Unit: 1624

pyrazolopyrimidines, in general, in a two-phase system. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Pursuant to *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Some experimentation is not fatal; the issue is whether the amount of experimentation is "undue"; see *In re Vaeck*, 20 USPQ2d 1438, 1444.

The analysis is as follows:

(A) Breadth of claims: Scope of the compounds. Owing to the starting material substituted pyrazole, three bicyclic pyrazolopyrimidines are embraced, pyrazolo[1,5-a]pyrimidines, pyrazolo[4,3-d]pyrimidines and pyrazolo[3,4-d]pyrimidines.

(B) The nature of the invention: The invention is a substituted pyrazolopyrimidine bicyclic core.

(C) Level of predictability in the art: It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity

is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(D) Direction or Guidance: That provided is very limited. Applicant provides three specific synthesis on pages 11-13 of zaleplon, a substituted pyrazolo[1,5-a]pyrimidines, under Examples 1-3 of the Specification, but does not show a process of making any other pyrazolopyrimidines. There is limited evidence in the Specification of a process of making pyrazolopyrimidines in general. Thus, there is no specific direction or guidance regarding said compounds specifically mentioned in the Scope.

The specification does not provide any support for the synthesis of substituted pyrazolopyrimidines, in general, in a two-phase system.

The availability of the starting material that is needed to prepare the invention as claimed is at issue here...As per MPEP 21'64.01 (b). A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening. The Court in *In re Ghiron*, 442 F.2d 985, 991,169 USPQ 723, 727 (CCPA 1971), made it clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. *In re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

(E) State of the Prior Art: A process of making substituted pyrazolo[1,5-a]pyrimidines are well documented in the art. So far as the examiner is aware, a process of making substituted pyrazolopyrimidines, in general, in a two-phase system of any kind have been made or used.

(F) Working Examples: Applicant shows Example 1-3, drawn to pyrazolo[1,5-a]pyrimidines, but no working examples were shown of pyrazolo[4,3-d]pyrimidines or pyrazolo[3,4-d]pyrimidines of any kind.

(G) Skill of those in the art: The ordinary artisan is highly skilled.

(H) The quantity of experimentation needed: Since there are very limited working examples as described above, the amount of experimentation is expected to be high and burdensome.

Due to the level of unpredictability in the art, the very limited guidance provided, and the lack of working examples, the Applicant has shown lack of enablement for the groups noted groups on Formula i. MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/
Examiner, Art Unit 1624

/Brenda L. Coleman/
Primary Examiner, Art Unit 1624